5. 510(k) Summary

SEP 15 2006

Date: Amended September 6, 2006

Submitter: GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Allen D. Tabor
Quality & Regulatory Engineer
GE Medical Systems Information Technologies
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Device Trade Name: Mac-Lab/CardioLab/ComboLab/SpecialsLab System

Common/Usual Name: Cardiac Catheterization Laboratory System

Classification Names: 21 CFR 870.1425 *Programmable Diagnostic Computer*

Predicate Device: Mac-Lab/CardioLab EP/ComboLab System (K050093)

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The product will be available in the following configurations: Mac-Lab application only, CardioLab application only, SpecialsLab only, or a combination of both CardioLab and Mac-Lab applications, marketed as ComboLab. Products designated as SpecialsLab are identical to the Mac-Lab, CardioLab or ComboLab Systems with the exception they will support fewer options. The SpecialsLab System performs the same intended use as the Mac-Lab, CardioLab or ComboLab, executes the same software, and runs on the same hardware. The product "CardioLab" was identified as "CardioLab EP" in the predicate device 510(k) submission K050093.

**The Mac-Lab System:** The Mac-Lab System is intended for monitoring, calculating and recording cardiovascular data from patients undergoing invasive cardiac catheterization procedures. The data may be manually entered or acquired via interfaced devices. Data includes: ECG waveforms, heart rate, pulse oximetry ($SpO_2$), respiration rate, EtCO2, temperature, valve gradients and areas, cardiac output, hemodynamic measurements, invasive and noninvasive blood pressure, procedural information, and optional intracardiac electrocardiogram (IECG). The information can be displayed, trended, stored, printed, and or transmitted to other networked hospital information systems. The system does not transmit alarms or arrhythmias and does not have arrhythmia detection capabilities.

Interfaced devices the system may acquire, amplify, display and record anatomical and physiological data from includes equipment typically used in conjunction with these procedures, such as imaging and data devices (e.g. X-ray, ultrasound, magnetic resonance, computed tomography, positron emission tomography, nuclear medicine, 12 lead ECG and information systems.)

**Device Description**

**The CardioLab System:** The CardioLab System is intended to acquire, filter, digitize, amplify, display and record the electrical signals. Signal types acquired include ECG signals, direct cardiac signals, temperature, EtCO2, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, and generate reports on the data. Additionally, the system may acquire, amplify, display and record data received from other interfaced medical devices typically used during these procedures, such as imaging devices and ablation generators (i.e. RF and cryogenic).

The CardioLab System does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze data acquired during the procedure. The CardioLab System does not transmit alarms or arrhythmias and does not have arrhythmia detection capabilities.

Interfaced devices the system may acquire, amplify, display and record anatomical and physiological data from includes equipment typically used in conjunction with these procedures, such as imaging and data devices (e.g. X-ray, ultrasound, magnetic resonance, computed tomography, positron emission tomography, nuclear medicine, 12 lead ECG and information systems.)

**The ComboLab System:** The ComboLab configuration is the combination of both CardioLab and Mac-Lab applications, though only one application may be used at a time (CardioLab for electrophysiological lab cases and Mac-Lab for catheterization lab cases).

**The SpecialsLab System:** The SpecialsLab is the same as the Mac-Lab, CardioLab or ComboLab systems. The SpecialsLab System is intended for use in either a catheterization laboratory or electrophysiological laboratory and related specialty laboratories under the direct supervision of a licensed healthcare practitioner. SpecialsLab executes the same software, and runs on the same hardware. Products designated SpecialsLab will support fewer options than the Mac-Lab, CardioLab or ComboLab.

**Intended Use**

**Mac-Lab System:** The Mac-Lab System is intended for monitoring, calculating and recording cardiovascular data from patients undergoing invasive cardiac catheterization procedures. The data may be manually entered or acquired via interfaced devices. Data includes: ECG waveforms, heart rate, pulse oximetry ($SpO_2$), respiration rate, EtCO2, temperature, valve gradients and areas, cardiac output, hemodynamic measurements, invasive and noninvasive blood pressure, procedural information, and optional intracardiac electrocardiogram (IECG). The information can be displayed, trended, stored, printed, and or transmitted to other networked hospital information systems. The system does not transmit alarms or arrhythmias and does not have arrhythmia detection capabilities.

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**CardioLab System:** The CardioLab System is intended to acquire, filter, digitize, amplify, display and record the electrical signals. Signal types acquired include ECG signals, direct cardiac signals, temperature, EtCO2, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, and generate reports on the data. Additionally, the system may acquire, amplify, display and record data received from other interfaced medical devices typically used during these procedures, such as imaging devices and ablation generators (i.e. RF and cryogenic).

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**ComboLab System:** The ComboLab System is the combination of the both the Mac-Lab and CardioLab systems. The ComboLab System is intended for use in either a catheterization laboratory or electrophysiological laboratory and related specialty laboratories under the direct supervision of a licensed healthcare practitioner. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab System, although only one may be used at a time.

**SpecialsLab System:** The SpecialsLab is the same as the Mac-Lab, CardioLab or ComboLab systems.. The SpecialsLab System is intended for use in either a catheterization laboratory or electrophysiological laboratory and related specialty laboratories under the direct supervision of a licensed healthcare practitioner. SpecialsLab executes the same software, and runs on the same hardware. Products designated SpecialsLab will support fewer options than the Mac-Lab, CardioLab or ComboLab.

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**Technology**

The proposed Mac-Lab/CardioLab/ComboLab/SpecialsLab System employs the same functional scientific technology as the predicate device Mac-Lab/CardioLab EP/ComboLab System (K050093).

**Test Summary**

The Mac-Lab/CardioLab/ComboLab/SpecialsLab System complies with the voluntary standards as detailed in Section 17.1 of this submission, "Specific Standards and Guidance's". The following quality assurance measures are applied to the development of the device and the results thereof used in the determination of substantial equivalence to the predicate device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Clinical Use Validation
- Integration Testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental Testing

No clinical performance data has been used to support the substantial equivalence claims

**Conclusion**

The results of these measurements demonstrate that the Mac-Lab/CardioLab/ComboLab/SpecialsLab System is as safe, as effective, and performs as well as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2006

GE Medical Systems Information Technologies
c/o Mr. Allen D. Tabor
Quality & Regulatory Engineer
GE Healthcare Interventional, Surgical & Cardiology
8200 West Tower Avenue
Milwaukee, Wisconsin 55223

Re: K061741
Trade Name: Mac-Lab/CardioLab/ComboLab/SpecialsLab System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: September 6, 2006
Received: September 8, 2006

Dear Mr. Tabor:

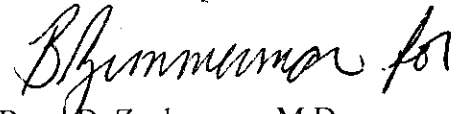
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Prescription Use__X__ AND/OR Over-The-Counter Use____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ivision Sign-Off)
vision of Cardiovascular Devices
10(k) Number K061741